JUL 1 7 2001

K011581

XI. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS. May 30, 1997. [Separate Pages]

I.* Submitter: Greg Wiita, Amertek Medical, Inc., 2655 North Ocean Drive, Singer Island, Florida 33404.

II. Classification Names and numbers: Acc. to Ultrasound Probe, Stepping Device, Code ITX

III. Common/Usual Name: Stepping and Stabilization Device

IV. Proprietary Names: Amertek™ Brachytherapy Template

V. Establishment Registration Number: in process

VI. Classification: Acc. to ultrasonic transducer, Class II, CFR 892.1570

VII. Substantial Equivalence: Amertek™ is substantially equivalent (and nearly identical to the device cleared under K-972152. It is sold in sterile form like the Civco Brachytherapy Template cleared under K-970514. It is also equivalent to devices cleared for marketing by the 510(k) process under K-864807 (Teknar), K-871413 (Civco), K-913293 (Mick Radio-Nuc.) and K-963302 (Tayman Medical).

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use, as the equivalent devices the classified device and those cleared for marketing by the 510(k) process under K802032 and K913293 (Mick Radio-Nuclear), under K864807 (Teknar Corp.) and others listed above.

2. The technological characteristics for this product are the same as those for the predicate devices and those currently on the market.

3. Descriptive information provided shows that the materials from which Amertek™ is made are substantially equivalent those of similar products, used for identical purposes, currently on the market.

4. The FDA "Decision-Making Process" chart was used and appears in Attachment IV.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2001

Mr. Greg Wiita
President
Amertek Medical, Inc.
2655 North Ocean Drive
SINGER ISLAND FL 33404

Re: K011581
Ameritek Brachytherapy Template
(Seeding Device; Probe Stabilization Device)
Dated: April 24, 2001
Received: May 23, 2001
Regulatory Class: II
21 CFR 892.1570/Procode: 90 ITX

Dear Mr. Wiita:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

VIII.1 Indications for Use: [Separate Page]

Note: This is the same "Indications for Use" as for the original except *(or other)* is added after "prostate" since the applications of brachytherapy have expanded.

510(k) Number: NA

Device Name: Amertek™ Brachytherapy Template

The Amertek Template is designed to allow precision ultrasound probe alignment and radioactive seed implantation in brachytherapy treatments. A specific application is the treatment of prostate (or other) cancer.

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011581